January 8, 2004

Review of K033736

Submitted by Concentric Medical, Inc.

Reviewed by Richard P. Felten, DGRND, GSDB

This Premarket Notification (510(k)) has been submitted by Concentric Medical to request market clearance for their MERCI Retriever. The company is requesting clearance for the specific indication for use of "to restore blood flow in the neurovasculature by removing thrombus in patients experiencing an ischemic stroke".

Concentric has submitted this 510(k) for this indication as an expansion of their already cleared indications for use for the Concentric Retriever (K030476). The retriever has been previously cleared for the indications for use of "retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral, and coronary vascular systems".

The MERCI Retriever, which is the specific device being reviewed in this application is essentially identical to the previously cleared device. Both the predicate device and the device described in this application are single use, Ethylene Oxide (EtO) gas sterilized, percutaneously delivered devices. Both catheters are manufactured from nitinol, and platinum and both have a hydrophilic coating. The predicate devices have 3 different configurations while the system described in this application is limited to 2 configurations. The configurations that are the same for the predicate and this application are identified as models X5 and X6.

In terms of functional design, the catheter ends in a helically coiled tip which is used to grasp the foreign body for the predicate use and to grasp the clot in the present application. Both the model X5 and X6 have 5 loops in the coil with the distal tip core wire having a diameter of 0.0026 inches. The distal loop diameter for both models is 1.1 mm and the proximal loop diameter is 2.7 mm for both models. The only difference between the X5 and X6 is in the diameter of the loop wire itself with the X5 having a diameter of 0.0040 inches and the X6 having a diameter of 0.0050 inches.

The Concentric Retriever is a flexible, tapered nickel titanium (nitinol) wire with a helical shaped distal tip. The tip is covered with a platinum radiopaque coil which facilitates fluoroscopic visualization. The rest of the wire is covered with a hydrophilic covered polymer sleeve which helps ease movement of the wire through a micro catheter.

A Concentric Balloon Guide Catheter is also used in the retrieval process. The Guide Catheter is used to reach the occlusion site and is used to deliver contrast medium to the site to visualize the vessel and target treatment site. Once this is performed a guide wire contained within a micro catheter is advanced through the Balloon Catheter to the

occlusion site and beyond the occlusion. The guide wire is then withdrawn and angiography is performed through the micro catheter. Once this is completed the Concentric Retriever is advanced through the micro catheter beyond the occlusion, the micro catheter is then withdrawn leaving the Retriever beyond the occlusion. The Retriever is then slowly withdrawn back through the occlusion allowing the helical coil to ensnare the clot. Once the clot is ensnared, the Balloon Catheter is inflated to control blood flow and then the micro catheter and Retriever are withdrawn into the Balloon Catheter. Aspiration is applied to the Balloon Catheter during this process to help ensure complete thrombus removal. Once complete evacuation of the thrombus is confirmed, the balloon is deflated and a final angiogram is performed to confirm improved blood flow.

An extensive series of bench tests were performed to establish physical performance specifications for the Retriever. This testing included:

a. Tensile strength, force needed to break the wire/coil joints; acceptance based on similar devices which is must not fail below 0.5 lbs. of force: Company tested 17 devices with average force needed to break joint established at 0.74 lbs. and all tested systems exceeded the 0.5 lbs. acceptance criteria.
b. Torque strength, number of rotations needed produce fracture at distal tip, acceptance criteria was set at 10 rotations, however it should be noted that use of the Retriever does not require rotation of the device to ensnare thrombus: Company tested 10 devices with average rotation to failure being 33 rotations and all meet minimum of 10.
c. Torqueability, how distal tip responds to proximal rotation: Company tested 10 devices. Again the Retriever is not intended to rotate during use. Company established that no more than 15 rotations should be needed to rotate the tip completely. Test established that this could occur with an average of 7.5 rotations.
d. Tip flexibility, amount of force needed to deflect distal tip; acceptance was no more than 10 g of force to deflect tip 45 degree, this is assumed to be a low enough force that tip could not therefore penetrate vessel wall: Company tested 10 devices with average force needed to deflect tip being 2.03 g and all device meet the 10 g acceptance criteria.
e. Coating lubricity and durability, ease of movement: Company tested 10 devices by determining force needed to move Retriever through a micro catheter. Even after 5 cycles Retriever Catheter was easily moved through a tortuous path. In addition, animal studies have shown ease of movement and examination of catheters after animal studies has shown the durability of the coating.

The Concentric Balloon Guide Catheter was also extensively tested for physical safety. Testing included:

a. Tensile test of joints at the hub/shaft; shaft/distal tip; and dilator hub/shaft; acceptance was 15 N for the hub/shaft joints and 10 N for the tip/shaft: Company

tested 10 devices, with the hub/shaft joints requiring an average of 53 N to fail and the tip/shaft 12 N to fail. All devices passed acceptance criteria.

b. Air leak test, catheter shall not leak air on aspiration per EN ISO 10555-1; Company tested 10 devices with 9 passing. One device had the luer lock threads damaged and was therefore not tested.

c. Liquid leak test, catheter shall not leak fluid under EN ISO-10555-1; Company tested 10 devices and all passed with no leakage.

d. Torque test, establish that a 1:1 ratio exists for manipulation of balloon catheter during placement; Company tested 10 catheters and all 10 showed a 1:1 ratio for manipulation.

e. Kink resistance, catheter will not kink when bent to a 0.5 inch diameter with dilator in place. With dilator removed catheter should withstand a 1.5 inch diameter bend. Company tested 10 catheters and all passed both tests.

f. High pressure leak test, catheter withstand 300 psi with leaking; Company tested 10 catheters and all passed the 300 psi test with no leaks observed and no visible damage to catheter observed.

g. Flow rate test, this test has no acceptance criteria but testing was performed to accumulate data on flow, 5 catheters were used for this test.

h. Balloon symmetry, show balloon symmetrical on inflation when inflated using 0.8 ml of inflation volume; Testing of 6 catheters established that no catheter had a difference greater than 2 mm in opposing radii. This value is accepted as demonstrating symmetry in balloon inflation.

i. Balloon inflation/deflation time, using 0.8 ml this should be performed within 5 seconds and deflation time should be within 30 seconds; Testing of 9 catheters demonstrated that these times could be achieved with all catheters.

j. Balloon catheters were tested to establish that specific inflation volumes would result in predicable inflation size diameters for the balloon. Six catheters were tested and all were shown to meet the acceptance criteria tolerance values.

k. Burst/leak test of inflated balloon to show that inflation did not affect these parameters. These tests were performed under unconstrained (represents use in a vessel) and constrained (fix rigid tube) conditions. The constrained test is considered a worst case test. Five of six catheters meet unconstrained criteria and nine of ten constrained meet criteria. One catheter in each group was withdrawn from testing due to manufacturing error which have resulted in changes in manufacturing steps.

l. Balloon fatigue test, this is based on a CDRH guidance for Catheters requiring forty inflation/deflation cycles; Company tested 10 catheters and all passed this test.

Regarding device use and device related problems, 144 subjects have been enrolled into this study. Of these subjects, 137 have been treated with the MERCI device. The clinical data being evaluated for this application contains acute data for 114 subjects.

In terms of device problems, 137 subjects have been treated using the MERCI device under the Concentric Approved IDE's and 2 subjects have been treated using the MERCI device in a separate physician sponsored study. Of the total of 139 device uses, there

have been 12 retriever fractures, 9 fractures of the model X6 and 3 fractures of the model X5. These fractures have been described by the investigators as 10 detachments within the patient requiring intervention and 2 fractures that did not result in a detachment and therefore did not require intervention.

Of the reported 12 retriever fractures, 2 have been identified as possibly resulting in patient related complications. One of these fractures was determined to be possibly associated with contrast extravasation indicative of subarachnoid hemorrhage. The investigator determined this was possibly the result of the introduction of other devices used in retrieving the facture tip. This patient died 2 days post procedure.

The other incident determined to be possibly associated with patient adverse event and complications was in a patient in which on the third pass, the investigator experienced resistance upon attempting to withdrawal the device. When the physician exerted additional pressure the tip detached. While attempting to retrieve the tip, it was noted following a dye injection a small amount of contrast extravasation and physician determined that a small dissection of the vessel had occurred. All further interventions were stopped. Immediately post procedure patient condition was unchanged from pre-procedure status but status did continue decline and patient expired the next day.

Of the 10 detachment failures, 7 of these occurred in the originally manufactured devices. Subsequent to these failures, Concentric modified the tool used to form the helically tip. Since introducing this modification, there have been 3 detachments. Based on discussions with the investigators involved in these detachments, Concentric determined that 2 of the original 7 failures had occurred as a result of excessive torquing exceeding the recommended limit in the device IFU. For all 3 of the failures of devices manufactured using the modified forming tool, all 3 of these were the result of over torquing beyond the IFU limit.

To address these most recent failures, Concentric has again revised the IFU for the MERCI Retriever. This revision now limits the number of revolutions to 2 revolutions in the counterclockwise direction and 5 revolutions clockwise. In addition to this precaution regarding torquing, the IFU also limits the number of attempts that can be made using the retriever to 6 retrieval attempts defined as catheter advancement, torquing, and complete withdrawal.

The IFU provides clear step-by-step directions for use of the retriever for clot removal. These directions include site of introduction of the catheter, information on use of the Concentric Balloon Guide Catheter, the sequence of steps regarding placement of the guidewire and microcatheter and use of angiography to identify the clot site and the individual steps used to position the MERCI Retriever, its withdrawal, and Balloon inflation to stop blood flow during withdrawal.

The information contained in this application, combined with the initial catheter characterization information provided in the approved IDE's, has clearly described the MERCI Retriever System, and provided bench test data to support the performance

characteristics and safety of this system. This application also contains the appropriate comparison table showing the relationship between the devices used in the clinical study for clot removal versus the previously cleared devices for retrieval of foreign bodies.

At this time there are no issues outstanding regarding device description and its use.